

PCT

REC'D 18 JAN 2005

RAPPORT D'EXAMEN PRELIMINAIRE INTERNATIONAL
(article 36 et règle 70 du PCT)

Référence du dossier du déposant ou du mandataire	POUR SUITE A DONNER voir la notification de transmission du rapport d'examen préliminaire international (formulaire PCT/PEA/416)	
Demande internationale No. PCT/FR 03/02909	Date du dépôt international (<i>jour/mois/année</i>) 03.10.2003	Date de priorité (<i>jour/mois/année</i>) 04.10.2002
Classification internationale des brevets (CIB) ou à la fois classification nationale et CIB A61K9/20		
Déposant ETHYPHARM et al.		

1. Le présent rapport d'examen préliminaire international, établi par l'administration chargée de l'examen préliminaire international, est transmis au déposant conformément à l'article 36.
2. Ce RAPPORT comprend 4 feuilles, y compris la présente feuille de couverture.

☐ Il est accompagné d'ANNEXES, c'est-à-dire de feuilles de la description, des revendications ou des dessins qui ont été modifiées et qui servent de base au présent rapport ou de feuilles contenant des rectifications faites auprès de l'administration chargée de l'examen préliminaire international (voir la règle 70.16 et l'instruction 607 des Instructions administratives du PCT).

Ces annexes comprennent feuilles.

3. Le présent rapport contient des indications et les pages correspondantes relatives aux points suivants :

- I ☒ Base de l'opinion
- II ☐ Priorité
- III ☐ Absence de formulation d'opinion quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle
- IV ☐ Absence d'unité de l'invention
- V ☒ Déclaration motivée selon la règle 66.2(a)(ii) quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration
- VI ☐ Certains documents cités
- VII ☐ Irrégularités dans la demande internationale
- VIII ☐ Observations relatives à la demande internationale

Date de présentation de la demande d'examen préliminaire internationale 26.04.2004	Date d'achèvement du présent rapport 17.01.2005
Nom et adresse postale de l'administration chargée de l'examen préliminaire international <div style="display: flex; align-items: center;"> <div> Office européen des brevets D-80298 Munich Tél. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div>	Fonctionnaire autorisé Villa Riva, A N° de téléphone +49 89 2399-8404



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**RAPPORT D'EXAMEN
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6. Observations complémentaires, le cas échéant :

V. Déclaration motivée selon l'article 35(2) quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration

1. Déclaration

Nouveauté	Oui:	Revendications	1-22
	Non:	Revendications	
Activité inventive	Oui:	Revendications	1-22
	Non:	Revendications	
Possibilité d'application industrielle	Oui:	Revendications	1-22
	Non:	Revendications	

2. Citations et explications

voir feuille séparée

Concernant le point V**Déclaration motivée quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration**

Dans la présente demande, le problème technique est d'obtenir des particules enrobées suffisamment résistantes aux sollicitations mécaniques pendant la compression directe, avec des bonnes propriétés de libération du principe actif et sans ajouter des quantités excessives d'excipients.

La solution proposée comprend l'utilisation de glycérides polyglycosylés ajoutés au polymère entérique dans la couche intermédiaire et d'un enrobage hydrodispersible contenant un désintégrant.

Quoique individuellement ils soient décrits dans l'art antérieur, la combinaison entre tous les composants n'est ni décrite ni suggérée. Pour cette raison, les revendications 1-22 sont considérées satisfaire les conditions requises par le PCT à l'égard de la nouveauté et de l'activité inventive.

Translation

Rec'd PCT/PTO

04 APR 2005

PCT/FR2003/002909

INTERNATIONAL COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR2003/002909	International filing date (day/month/year) 03 octobre 2003 (03.10.2003)	Priority date (day/month/year) 04 octobre 2002 (04.10.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/20		
Applicant ETHYPHARM		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of _____ sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 26 avril 2004 (26.04.2004)	Date of completion of this report 17 January 2005 (17.01.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/FR2003/002909

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-24, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages 1-22, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/FR 03/02909

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-22	YES
	Claims		NO
Inventive step (IS)	Claims	1-22	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims		NO

2. Citations and explanations

In the present application, the technical problem is that of providing coated particles, which are sufficiently resistant to mechanical stress during direct compression and have good active-principle release properties but do not contain excessive amounts of carrier.

The proposed solution involves the use of polyglycosylated glycerides, which are added to the enteric polymer in the intermediate layer, and the use of a water-dispersible coating, which contains a disintegrating agent.

Even though they are described individually in the prior art, the combination of all of these components is not described or suggested therein. For this reason, claims 1-22 are considered to fulfil the PCT requirements of novelty and inventive step.